UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

DEFENDANTS TORRENT PHARMACEUTICALS LTD. AND TORRENT PHARMA, INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

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Defendants Torrent Pharmaceuticals Ltd. and Torrent Pharma, Inc. (collectively, "Torrent") respectfully submit this Memorandum of Law in Support of their Motion for Partial Summary Judgment.

INTRODUCTION

In addition to the myriad reasons why Defendants are entitled to summary judgment laid out in the TPP Trial Defendants' Omnibus Motion for Summary Judgement, (the "Omnibus Motion"),[1] filed contemporaneously with this motion and incorporated herein by reference, Torrent is separately entitled to summary judgment on three issues.[2]

First, Torrent is entitled to summary judgement on Plaintiffs' fraud claims. These claims require Plaintiffs to show that Torrent had scienter, *i.e.*, that, at a minimum, Torrent had actual knowledge of an alleged falsity and, for States with a stricter standard, that it also acted with an intent to deceive. But Plaintiffs have

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[1] Capitalized terms have the same meaning here as in the Omnibus Motion and the accompanying Statement of Undisputed Material Facts and exhibits.

[2] This Motion concerns certain of the claims designated in the Court's Case Management Order No. 32 (the "TPP Trial Claims"); specifically, the claims of Plaintiff MSP Recovery Claims, Series LLC ("MSPRC"), as class representative of TPP Breach of Warranty Subclass Group B, TPP Breach of Implied Warranty Subclass Group D, TPP Fraud Subclass Group A, and TPP State Consumer Protection Laws Subclass Group A (collectively, the "TPP Classes"). ECF No. 2343 at 1-2. Accordingly, this motion is limited to the TPP Trial Claims, and is presented without waiver of any arguments for summary judgment with respect to any other claims asserted by any Plaintiff as to any Defendants in this multi-district litigation.

introduced no evidence that Torrent had any knowledge of the possibility for NDMA or NDEA formation in the valsartan active pharmaceutical ingredient ("API") it purchased from Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") until ZHP told Torrent about the issue on August 3, 2018, let alone that Torrent somehow acted with an intent to deceive. Because there is no dispute of material fact as to Torrent's lack of scienter, Plaintiffs' fraud claims against Torrent fail as a matter of law.

Second, Torrent is entitled to summary judgement on Plaintiffs' claims seeking punitive damages. States that allow punitive damages for breach of warranty, fraud, or consumer protection claims require Plaintiffs to meet an exacting state-of-mind or culpability standard. Because Plaintiffs cannot show that Torrent acted with the requisite level of knowledge or intent to deceive, Plaintiffs likewise cannot prove that they are entitled to punitive damages, and Torrent is entitled to summary judgment as to any claims for punitive damages.

Third, Torrent is entitled to summary judgment as to each of Plaintiffs' claims premised on the allegation that Torrent's valsartan-containing drugs ("VCDs") were "adulterated" within the meaning of the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). Whether a drug is "adulterated" within the meaning of the FDCA is a determination that only the United States Food and Drug Administration ("FDA") can make. However, the FDA has never found

Torrent's VCDs to be adulterated, and Plaintiffs have not introduced any evidence to the contrary. As a result, Torrent is entitled to summary judgment on any claims alleging that Torrent's VCDs were adulterated.

BACKGROUND

The facts relevant to this motion are set forth in detail in Defendants' Omnibus Motion and the accompanying Statement of Undisputed Material Facts ("SUMF"), which are incorporated herein.

LEGAL STANDARD

Torrent incorporates by reference the Legal Standard outlined in the Omnibus Motion. *See* Omnibus Motion at 7.

ARGUMENT

I. PLAINTIFFS' FRAUD CLAIMS FAIL BECAUSE THERE IS NO EVIDENCE THAT TORRENT ACTED WITH SCIENTER.

As the Court has recognized, to prove a fraud claim for TPP Fraud Subclass Group C, Plaintiffs must prove, at a minimum, that Torrent had "knowledge of falsity" of any alleged false statements. ECF No. 2261 at 32.[3] Additionally,

[3] *See also Kirst v. Ottosen Propeller & Accessories Inc.*, No. 3:16-CV-00188-TMB, 2018 WL 9943555 at *7 n.76 (D. Alaska June 20, 2018) (Alaska); *Star City Sch. Dist. v. ACI Bldg. Sys., LLC*, 844 F.3d 1011, 1016 (8th Cir. 2017) (Arkansas); *Greenway Nutrients, Inc. v. Blackburn*, 33 F. Supp. 3d 1224, 1256 (D. Colo. 2014) (Colorado); *Equitas Disability Advocs., LLC v. Bryant*, 134 F. Supp. 3d 209, 218 (D.D.C. 2015) (District of Columbia); *Myers v. Provident Life & Accident Ins. Co.*, 472 F. Supp. 3d 1149, 1178 (M.D. Fla. 2020) (Florida); *In re Parkinson Seed Farm, Inc.*, 640 B.R. 218, 257 (Bankr. D. Idaho 2022) (Idaho); *First Dakota Nat'l Bank v. Ruba*, 412 F. Supp. 3d 1153, 1160 (D.S.D. 2019) (Iowa); *Xiao Wei Yang*

certain jurisdictions in TPP Fraud Subclass Group c (Iowa, Louisiana, North Carolina, South Dakota, Virginia, and D.C.) require even greater culpability—specifically, an intent to deceive beyond mere knowledge.[4] Plaintiffs cannot survive summary judgment under any version of the scienter requirement because

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Catering Linkage in Inner Mongolia Co. Ltd v. Inner Mongolia Xiao Wei Yang USA, Inc., 340 F. Supp. 3d 70, 83 (D. Mass. 2018) (Massachusetts); *Clements Auto Co. v. Serv. Bureau Corp.*, 444 F.2d 169, 175 (8th Cir. 1971) (Minnesota); *Perry v. Gold & Laine, P.C.*, 371 F. Supp. 2d 622, 627 (D.N.J. 2005) (New Jersey); *In re Welspun Litig.*, No. 16 CV 6792 (VB), 2019 WL 2174089 at *15 (S.D.N.Y. May 20, 2019) (New York); *Great Am. Emu Co., LLC v. E.J. McKernan Co.*, 509 F. Supp. 3d 528, 538-539 (E.D.N.C. 2020) (North Carolina); *Starkey v. JPMorgan Chase Bank, NA*, 573 F. App'x 444, 447 (6th Cir. 2014) (Ohio); *Pizza Inn, Inc. v. Odetallah*, 631 F. Supp. 3d 1051, 1063 (W.D. Okla. 2022), *appeal dismissed*, No. 22-6167, 2022 WL 19404932 (10th Cir. Dec. 6, 2022) (Oklahoma); *Guilbeault v. R.J. Reynolds Tobacco Co.*, 84 F. Supp. 2d 263, 268-269 (D.R.I. 2000) (Rhode Island); *Dasler v. Knapp*, No. 2:21-CV-135, 2021 WL 4134398 at *9 (D. Vt. Sept. 10, 2021) (Vermont); *King Cnty. v. Viracon, Inc.*, No. 2:19-CV-508-BJR, 2021 WL 3053211 at *3 (W.D. Wash. July 20, 2021), *motion for relief from judgment denied*, No. 2:19-CV-508-BJR, 2022 WL 782572 (W.D. Wash. Mar. 15, 2022), and *reconsideration denied*, No. 2:19-CV-508-BJR, 2022 WL 838508 (W.D. Wash. Mar. 21, 2022) (Washington).

[4] *See Kitt v. Cap. Concerts, Inc.*, 742 A.2d 856, 860 (D.C. 1999) ("The essential elements of common law fraud" include "the intent to deceive") (D.C. law); *Seibert v. Noble*, 499 N.W.2d 3, 7 (Iowa 1993) ("Among the elements of fraud is an intent to deceive, which the other party relies upon with resulting damages to the relying party.") (Iowa law); *Chateau Homes by RJM, Inc. v. Aucoin*, 97 So. 3d 398, 404 (La. App. 5 Cir, 2012), *writ denied*, 98 So. 3d 872 (La. 2012) ("For purposes of the tort of fraud, the intent to deceive is a specific intent.") (Louisiana law); *Forbis v. Neal*, 361 N.C. 519, 526–27 (2007) (actual fraud requires an "intent to deceive") (North Carolina law); *Est. of Johnson ex rel. Johnson v. Weber*, 898 N.W.2d 718, 729 (S.D. 2017) (fraud requires proof the defendant "made the representation with intent to deceive") (South Dakota); *Owens v. DRS Auto. Fantomworks, Inc.*, 288 Va. 489, 497 (2014) (common law fraud requires "intent to mislead") (Virginia law).

they have presented no evidence of any knowledge on Torrent's part of the potential for NDMA or NDEA contamination, let alone an intent to deceive. *See In re TMJ Implants Prod. Liab. Litig.*, 880 F. Supp. 1311, 1317 (D. Minn. 1995), *aff'd sub nom. In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 113 F.3d 1484 (8th Cir. 1997) (granting summary judgment on fraudulent misrepresentation and omission claims regarding safety of silicone breast implants because plaintiff offered no evidence of defendant's knowledge of the danger).

On the contrary, the evidence reflects that Torrent was unaware of the NDMA or NDEA in the valsartan API it purchased from ZHP or the potential for NDMA or NDEA formation until ZHP notified Torrent on August 3, 2018. SUMF ¶ 45. Moreover, prior to that notification, Torrent conducted regular testing of ZHP's API and audited ZHP's facilities at appropriate intervals, and neither revealed anything to suggest the presence of NDMA or NDEA in the API. SUMF ¶¶ 31, 45.

The evidence also reflects that prior to July 2018, there was no FDA standard, testing methodology, or other regulatory or industry standard or requirements pertaining to limits of NDMA or NDEA in VCDs that would have alerted Torrent to the potential for the formation of NDMA or NDEA in valsartan API before ZHP's notification. SUMF ¶ 73. Moreover, in the years leading up to the recall, Torrent's facilities consistently passed FDA inspections, complied with

cGMPs, and conducted regular testing of its products to ensure the product met all specifications. SUMF ¶¶ 25-31.

Harris v. Pfizer Inc., another case involving nitrosamine impurities in pharmaceutical drugs, is instructive. 586 F. Supp. 3d 231 (S.D.N.Y. 2022). There, plaintiffs alleged "that nitrosamine had been detected in other drugs by 2018, and that one of [the defendant's] distributors was warned in October of 2020 that its supply of varenicline was at risk of contamination as well." *Id.* at 241. The court held that this "at most only show[ed] that [the defendant] may have known that its medication was at risk of contamination by late 2020," but did not "show that [the defendant] knew or believed that [the drug] was actually contaminated." *Id.* (emphasis in original).

The situation here is even more clear cut: there is no evidence whatsoever that Torrent may have known that their valsartan API was at risk of contamination at any point before ZHP notified Torrent of potential contamination in August 2018.[5] SUMF ¶¶ 31, 45; *see also In re Fosamax Prod. Liab. Litig.*, 807 F. Supp. 2d 168, 188-89 (S.D.N.Y. 2011), *aff'd*, 509 F. App'x 69 (2d Cir. 2013), and *aff'd*, 707 F.3d 189 (2d Cir. 2013) (granting summary judgment where plaintiffs "fail[ed]

[5] Although *Harris* concerned a brand drug, and thus the false statement itself may be different than this case, the issue of *knowledge* of falsity is the same as present here: did Pfizer *know* that there was a risk of contamination in its drug when it made an allegedly false statement? *Harris v. Pfizer Inc.*, 586 F. Supp. 3d 231, 241 (S.D.N.Y. 2022).

to allege that [the defendant] was aware of the FDA report [highlighting possible harmful effects], or the information contained therein" at the time the drug was prescribed). Because Plaintiffs have provided no evidence from which a reasonable jury could infer that Torrent acted with scienter, *i.e.*, had "knowledge of falsity" or an intent to deceive in addition to that knowledge, Plaintiffs' fraud claims fail as a matter of law. SUMF ¶ 45.

II. PLAINTIFFS CANNOT RECOVER PUNITIVE DAMAGES FROM TORRENT IN THE ABSENCE OF SCIENTER.

Without evidence that Torrent acted with scienter, Plaintiffs cannot prove that Torrent acted with the requisite culpability to support a punitive damages award.

The states that allow punitive damages for breach of warranty require Plaintiffs to show that Torrent demonstrated willful, malicious, or egregious misconduct. *See, e.g.*, *Hughes v. Segal Enterprises, Inc.*, 627 F. Supp. 1231, 1238 (W.D. Ark. 1986); *see also* Omnibus Brief at 39-40. The states that allow punitive damages for fraud or consumer protection claims likewise have state-of-mind or culpability standards. *See, e.g.*, *Johnston v. Vincent*, 359 So.3d 896, 919 (La. 2023); *Princes Point, LLC v. AKRF Eng'g, P.C.*, 94 A.D.3d 588, 589 (1st Dep't 2012); *K. Ronald Bailey Assoc. Co. v. Soltesz*, 2006 WL 1364019, at *3 (Ohio Ct. App. May 19, 2006); *Holeman v. Neils*, 803 F. Supp. 237, 242-43 (D. Ariz. 1992); *see also* Omnibus Brief at 40-43 Because Plaintiffs have no evidence of any

knowledge or intent on Torrent's part, Torrent is entitled to summary judgment with respect to Plaintiffs' claims for punitive damages.

III. PLAINTIFFS' CLAIMS PREMISED ON THE ALLEGATION THAT TORRENT'S VCDS WERE ADULTERATED CANNOT PROCEED.

Each of Plaintiffs' claims for breach of express and implied warranties, fraud, and consumer protection violations are based in part on allegations that the VCDs sold by Torrent were "adulterated." ECF No. 1708 ¶¶ 623-24, 628-30 (First Cause of Action), ¶ 641 (Second Cause of Action), ¶¶ 691-94 (Fifth Cause of Action), ¶¶ 727-28, 730-32, 737 (Seventh Cause of Action). Torrent is entitled to summary judgment as to any claims based on alleged adulteration because only the FDA can make a determination that Torrent's VCDs were adulterated within the meaning of the FDCA, and the FDA has never made such a determination for Torrent's VCDs.

A drug is deemed to be "adulterated" under specific circumstances outlined in the FDCA. *See* 21 U.S.C.A. § 351(a), (b), (c), (d). A violation of the FDCA requirements and a finding of adulteration can only be made by the FDA because "[t]he FDA—and the FDA alone—has the power and the discretion to enforce the FDCA." *Allergan, Inc. v. Athena Cosms., Inc.*, 738 F.3d 1350, 1359 (Fed. Cir. 2013). In the present case, the FDA has never found that Torrent's VCDs are adulterated. *See* SUMF ¶ 101. Plaintiffs have not—because they cannot—presented any evidence that the FDA ever found Torrent's VCDs to be adulterated.

In contrast, the FDA did determine that ZHP's valsartan API was adulterated and made this determination public on its website. *See* SUMF ¶ 96.[6]

Because the FDA has not determined that Torrent's VCDs are adulterated under the FDCA, neither the Court nor the jury can make such a determination in this case. *See Healthpoint, Ltd. v. Stratus Pharmaceuticals, Inc.*, 273 F. Supp. 2d 769, 787 (W.D. Tex. 2001) (declining to consider claims for injunctive relief "based on claims or arguments that [defendant] incorrectly labeled or misbranded" its product or "based on the argument that [defendant's] alleged low or varying level of [contaminant] render it adulterated" because "[c]laims of adulteration should be resolved by the FDA"). Plaintiffs' claims that Torrent's VCDs were adulterated "rel[y] on the FDCA or its implementing regulations as a critical element," which is the sole purview of the FDA. *Agee v. Alphatec Spine, Inc.*, No. 1:15-CV-750, 2017 WL 5706002, at *3-5 (S.D. Ohio Mar. 27, 2017), *aff'd*, 711 F. App'x 791 (6th Cir. 2018) (granting motion to dismiss misrepresentation claims that were "clearly dependent upon the FDCA to a degree that the claims would not exist but for the statute") (internal citations omitted).

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[6] Contrary to Plaintiffs' suggestions throughout this case, "product recalls do not create a presumption that FDA requirements have been violated." *Erickson v. Bos. Sci. Corp.*, 846 F. Supp. 2d 1085, 1093 (C.D. Cal. 2011). Nor does the mere issuance of a warning letter by the FDA create this presumption because "warning letters from the FDA do not mark the consummation of the agency's decision making process." *Rosas v. Hi-Tech Pharms.*, No. CV 20-00433-DOC-DFM, 2020 WL 5361878 at *3 (C.D. Cal. July 29, 2020).

Because only the FDA can determine that Torrent's VCDs are adulterated, and the FDA has never made such a determination, Plaintiffs' claims based on alleged adulteration of Torrent's VCDs fail as a matter of law.

CONCLUSION

For the foregoing reasons, Torrent respectfully requests that the Court grant its partial summary judgment motion.

Dated: December 22, 2023

Respectfully submitted,

/s/ Alexia R. Brancato

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CERTIFICATE OF SERVICE

I, Alexia R. Brancato, an attorney, hereby certify that on December 22, 2023, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Alexia R. Brancato
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